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ENERGY AND COMMERCE COMMITTEE

RANKING MEMBER
SUBCOMMITTEE ON
TELECOMMUNICATIONS AND
THE INTERNET

RESOURCES COMMITTEE

Congress of the United States

House of Representatives
Washington, DC 20515-2107
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The Honorable Spencer Abraham Secretary Department of Energy 1000 Independence Avenue S.W. Washington, D.C. 20585

Dear Mr. Secretary:

I am writing in regard to a report in the November 26, 2001 issue of <u>Inside Energy</u>, stating that Los Alamos National Laboratory (LANL) received a shipment of virulent anthrax from Northern Arizona University on October 26, 2001, even though LANL is not authorized to receive such shipments. I am also concerned that LANL may have misled both the LANL community and the Centers for Disease Control and Prevention (CDC) about its possession of this dangerous material.

As you may know, in 1996 I introduced H.R. 3033, the "Biological Weapons Control Act of 1996" with former Representative John Kasich, and Senator Hatch (S. 1606). The bill imposed requirements for the transfer of select agents and was later signed into law as part of the Anti-terrorism and Effective Death Penalty Act of 1996 (Section 511 of Public Law 104-132). If Congress had not passed this law, America would be largely in the dark with respect to who transfers or receives bioagents in this country. Last month the House took one more step in the battle against bioterrorism by voting to expand the 1996 law to require that all select agents be registered. I am concerned that LANL (and Northern Arizona University) may have violated the 1996 law. Consequently, I ask for your assistance in answering the following questions:

- 1) Current law requires any laboratory working with virulent anthrax samples to either be classified as a Biosafety Level-3 laboratory by the CDC or obtain a CDC exception permit or registration to handle the materials. LANL's laboratory reportedly is only classified as a Biosafety Level-2 laboratory, and it reportedly did not obtain a CDC exception permit or registration prior to receiving the anthrax sample. Is this true, and if so, have the appropriate law enforcement authorities been informed? If not, why not?
- 2) A November 21, 2001 Occurrence Report filed by LANL states that "LANL was in transition through internal processes to implement procedures to operate under an exception of 42 CFR 72.6 that allows transfer of select agent materials in support of law enforcement activities," which, had the processes been completed, would have allowed LANL to possess such samples.

a) Please provide all documentation associated with LANL's application for an exception to the law.

b) Has this exception since been granted, and if so, when and subject to what

conditions?

3) The November 21, 2001 Occurrence Report states that "the CDC has rendered a preliminary ruling that, because the work was in direct support of law enforcement, the shipment was exempt from the registration limitation, and was in full regulatory compliance." It is my understanding, however, that in order to be exempt from the registration limitation one has to apply to the CDC for an exemption prior to receiving a select agent. In fact, the November 21, 2001 Occurrence Report states that LANL was in the process of applying for such an exemption (but had not yet completed it) at the time it received the anthrax.

a) Please provide a copy of this preliminary ruling.

b) Which law enforcement agency requested LANL support in the anthrax investigation, and when? Did the request require the use of virulent anthrax samples? Please provide a copy of the request.

c) Has a final CDC ruling been issued? If so, please provide a copy.

- d) Does LANL now intend to work with live anthrax bacteria, even though it still doesn't have a Biosafety Level-3 facility?
- 4) Why did LANL request virulent anthrax from Northern Arizona University when it was not authorized to possess it?
- 5) Have the individuals who made and authorized the request been disciplined by LANL or DOE officials? If so, how, and if not, why not?
- 6) Please fully describe the process by which a request for biological samples such as anthrax is made for DOE facilities, as well as the security measures that are in place to ensure that the samples are not diverted. Please provide copies of the shipping documents that accompanied this shipment.
- 7) Has the University of California, which manages and operates LANL, been fined (or had a portion of their performance award fee withheld) or otherwise sanctioned by DOE for their failure to ensure compliance with the law? If not, why not?
- 8) Press reports (for example, see the November 15 2001 edition of <u>The New Mexican</u>) indicate that on November 14, 2001, LANL held a public meeting for the community in which it stated that it had chosen not to handle live anthrax bacteria until it built its new Biosafety Level 3 facility.

a) Why did LANL officials make this statement when in fact it was improperly

handling live anthrax bacteria at the time?

b) Why did LANL officials make this statement when in fact it had reportedly already initiated internal processes to obtain an exception to the law from CDC that would have allowed it to work on live bacteria prior to the new facility's construction? c) Have the individuals responsible for making this false statement been disciplined? If so, how, and if not, why not?

9) Please fully describe the procedure LANL has in place to identify violations of the

regulations governing select agents.

a) Under this procedure, which LANL official (please provide the name and title) is responsible for informing DOE when a violation of the regulations governing select agents occurs?

b) Under this procedure, how long after a violation is discovered should the LANL

official inform DOE and the CDC?

c) In the case of this particular violation of the regulations, who at LANL first informed DOE (please provide the name and title) that it had occurred? If it was not the LANL official described in a), why not?

d) On what date was DOE first informed of the violation?

e) If DOE was informed after the timeframe described in b), why did it take so long, and under what circumstances was DOE informed?

f) On what date was the CDC informed?

On November 20, 2001, John-Olav Johnsen, Acting Senior Technical Advisor for Bioscience at DOE Albuquerque Operations Office, wrote a letter to Mark L. Hemphill at the CDC stating that "an issue involving possible discrepancies of a Form EA-101 involving our contractor, Los Alamos National Laboratory (Requestor) and Northern Arizona University (Transferor) was brought to the attention of the Department of Energy, National Nuclear Security Administration (NNSA), Albuquerque Operations Office yesterday November 19, 2001."

- g) Why was the incident referred to as a "possible discrepancy", when in fact it was clear that it was a violation of the law?
- h) The letter also states that LANL "self-reported" the event to both DOE and the CDC. However, a press release issued by LANL on November 20 stated that LANL was responding to a query from the <u>Washington Post</u>. Did LANL "self-report" this incident to the CDC before or after the <u>Washington Post</u> called to ask about it?
- 10) On what date and under what circumstances did LANL decide to destroy a) the anthrax sample and b) the material in which it was packaged? Did LANL destroy any of the documentation that accompanied the shipment, and if so, why, since complete records are supposed to be kept of all such shipments?
- 11) Have tests been conducted to ensure that LANL or postal facilities that may have handled the sample are free of contamination? If so, what were the results, and if not, why not?
- 12)What security training (and how frequently is the training repeated and/or increased) is required for DOE laboratory scientists or other personnel who plan to work with

live biological samples such as anthrax to ensure that these individuals understand and comply with the law and associated regulations?

- 13)Are laboratory security officials involved in the preparation of the request for biological samples such as anthrax to ensure that the request for the materials is necessary, and that sufficient security exists onsite to properly store and handle them? If not, why not, given the potential danger these materials pose to public health and safety?
- 14) Press reports (for example, see the November 26, 2001 edition of <u>Inside Energy</u>) indicate that while LANL currently has a Biosafety Level-2 lab, it wishes to build a Biosafety Level-3 lab which would be authorized to receive samples of virulent anthrax. For each of these types of facilities, please provide:
 - a) the numbers of security guards that ensure the safety of the contents and personnel who work there
 - b) the security measures or procedures in place to ensure that shipments of unauthorized materials are not made or received, and that the entities sending/receiving the materials are authorized to do so
 - c) the physical security measures such as barriers, cameras or electronic security ID systems that are in place to ensure the security of the building
 - d) whether force-on-force exercises have been (or will be) conducted at these facilities to ensure that the security measures in place are sufficient.
- 15)Has LANL conducted an internal investigation to ensure that it does not possess any other dangerous biological materials it is not authorized to possess?
 - a) If so, what were the results, and if not, why not?
 - b) Has LANL ever been found to possess other biological agents it was not authorized to possess in the past? If so, please describe the circumstances associated with each such case, including whether law enforcement authorities were notified of the breach and whether disciplinary action was taken.
 - c) Has there been an investigation to determine whether this has ever occurred at other DOE facilities? If so, what were the results, and if not, why not?

Thank you very much for your attention to this important matter. Please provide your response by close of business January 2, 2002. Should you have any questions or concerns, please have your staff contact Dr. Michal Freedhoff of my staff at 202-225-2836.

Sincerely,

Edward J. Markey